

**Application No.:** 10/530,536  
**Filing Date:** January 23, 2006

### **REMARKS**

After entry of the present amendments, Claims 1-21, 23, 28-34, 43, and 48 will be pending. Claims 25-27 are canceled herein. Claim 1 is amended herein. The dependencies of Claims 28-32 are adjusted in view of the cancelation of Claim 27. New Claims 48-49 are added. Support for the amendments can be found in the claims as originally filed. No new matter is added. Each of the Examiner's rejections is addressed below.

#### **Restriction Requirement**

Applicants affirm the election of the claims of Group I, Claims 1-23, 25-34, and 43 without traverse.

#### **Rejections under 35 U.S.C. § 112**

The Examiner rejected claims 13, 16, and 22-23 under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejected Claims 13, 16, and 22-23 on the basis that it is unclear if the recited strains denote a trademark or trade name. Applicants submit that the phrases are not trade names but are microorganism deposit accession numbers with the Australian Government Analytical Laboratories (AGAL) culture collection. AGAL is now known as the Australian National Measurement Institute (NMI). AGAL/NMI is a recognized culture collection under the Budapest Treaty. The "HN017" and "HN019" text refers to the strain designation and the "NM97/09513" and "NM97/09515" refers to the deposit number for each strain. The recited dates refer to the deposit dates for the strains. Accordingly, Applicants request withdrawal of the rejection of Claims 13, 16, and 23.

The Examiner also rejected Claim 22 under 35 U.S.C. § 101. Claim 22 is canceled herein thereby mooted the rejection.

#### **Rejections under 35 U.S.C. § 102**

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). More particularly, a

finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994).

**Reps et al. fails to anticipate Claims 1-9 and 22**

Claims 1-9 and 22 stand rejected under 35 U.S.C. § 102(b) as anticipated by “Effect of high pressures on *Streptococcus salivaris* subsp. *Thermophilus*” by Reps et al. (hereinafter “Reps”).

Reps discloses a pressure treatment of 400 MPa for 30 minutes of various *S. salivarius* subsp. *Thermophilus* (SST) strains. Reps, section 2 of page 132. The activity of the various SST strains is measured after the pressure treatment to determine its effectiveness.

Reps discloses that “[i]t is a well-known fact that high pressures cause in-activation of lactic acid bacteria, prolongating thus milk durability by delay of the process of milk acidification.” Reps, page 132, second column. Thus, the goal of the pressure treatment in Reps is to cause inactivation of the lactic acid bacteria in order to increase the shelf life of the milk.

Claim 1 is amended herein to recite “wherein the food is subjected to the treatment pressure for about 5 minutes or less”. Reps fails to disclose this feature. Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 1 and its dependents.

This is more than an obvious variation of the disclosure of Reps. Reps is concerned with decreasing the SST bacteria with the pressure treatment in order to delay milk acidification. Reps discloses that “specifically prepared cultures, containing high-pressure sensitive SST bacteria, should be used.” Reps, page 132, first column. Further, the 30 minute pressure treatment was not effective on some strains of SST bacteria, and only decreased the activity of one strain by 35%. Reps, page 132, first column. Accordingly, based on the disclosure of Reps, there is no reason to shorten the pressure treatment step from 30 minutes to about 5 minutes or less because the skilled artisan would expect the shorter pressure treatment to be *less effective*, thereby resulting in a greater concentration of undesirable SST bacteria in the treated product and frustrating the purpose of Reps to delay milk acidification.

**Kortschack fails to anticipate Claims 1-2, 10, 14, 17-18, 21-22, 25, 33-34, and 43**

Claims 1-2, 10, 14, 17-18, 21-22, 25, 33-34, and 43 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,117,460 to Kortschack (hereinafter “Kortschack”).

Kortschack discloses a pressure treatment of 10 minutes that decreased the concentration of *lactobacilli* in smoked sausages. Col. 6, lines 1-5.

Claim 1 is amended herein to recite “wherein the food is subjected to the treatment pressure for about 5 minutes or less”. Kortschack fails to disclose this feature. Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 1 and its dependents.

This is also more than an obvious variation of the disclosure of Kortschack. Kortschack is concerned with increasing the shelf life of meats by treating the semifinished meat with a high pressure treatment. (“In any case the pH will remain stable in the semifinished products subsequent to the high-pressure treatment. There will be no further relevant biochemical processes.” Col. 4, ll. 63-65). Based on the disclosure of Kortschack, there is no reason to shorten the pressure treatment step from 10 minutes to about 5 minutes or less because no advantage of a shorter treatment is taught and the skilled artisan would expect the shorter pressure treatment to be less effective, thereby resulting in a greater concentration of undesirable bacteria in the treated meat. (“there is always the risk that due to microbiological risks faulty articles of poor quality or deficient color and storage stability may be obtained. Irrespective of the use of starter cultures it happens again and again that unforeseeable circumstances lead to deviations in quality.” See col. 5, lines 1-14).

**Rejections under 35 U.S.C. § 103(a)**

It is well settled that the Examiner “bears the initial burden of presenting a *prima facie* case of unpatentability...” *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); see also *M.P.E.P.* § 2143.03. Second, there must be a

reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness. Each of the combinations asserted by the Examiner is addressed below.

**The Examiner's Proposed Combination of Reps/Trujillo Fails To Make Claims 10 and 19-20 Obvious**

Claims 10 and 19-20 stand rejected under 35 U.S.C. § 103(a) as obvious over Reps in view of "Characteristics of stirred low-fat yoghurt as affected by high pressure" by Ancos (referred to as Trujillo by the Examiner). Applicants respectfully traverse the present rejection.

As discussed above, Reps fails to disclose the features of Claim 1. Ancos fails to make up for these deficiencies. Ancos discloses a pressure treatment of 100-400 MPa for 15 minutes. Thus, Ancos also fails to disclose or provide a reason for the skilled artisan to arrive at a process "wherein the food is subjected to the treatment pressure for about 5 minutes or less". Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

Further, the skilled artisan would have no reasonable expectation of success for the combination proposed by the Examiner. *Pharmastem Therapeutics v. Viacell, Inc.* 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007) (after *KSR*, Federal Circuit finds claims non-obvious for lack of indication of reasonable expectation of success for asserted combination). The Examiner found that it would have been obvious to one of ordinary skill in the art to add the *L. delbrueckii* ssp. *Bulgaricus* to the yogurt of Reps. However, Ancos discloses that the samples treated at 300 MPa and greater resulted in yogurt with lactobacilli cell counts below the acceptable levels. Thus, Ancos explicitly teaches away from pressure treating yoghurt with lactobacilli at pressures of **300 MPa or greater**. ("The results of the present research indicate that yoghurts treated at 300 MPa or higher reduced the viable cell counts of lactobacilli during the usual period of refrigerated storage to levels not permitted by law in many countries." Page 108, col. 1.). As a

result, the skilled artisan would not combine Ancos and Reps in the way suggested by the Examiner.

Thus, the skilled artisan would not have a reasonable expectation of success for using the strains of Ancos to the process of Reps, or make the asserted combination in the first place, because Ancos discloses that the high pressure treatment would inactivate an unacceptable amount of the lactobacilli strains.

**The Examiner's Proposed Combination of Kortschack/Gill Fails To Make Claims 11-13, 15-16, and 23 Obvious**

Claims 11-13, 15-16, and 23 stand rejected under 35 U.S.C. § 103(a) as obvious over Kortschack in view of U.S. Patent No. 6,379,663 to Gill et al. (hereinafter "Gill"). Applicants respectfully traverse the present rejection.

As discussed above, Kortschack fails to disclose the features of Claim 1. Gill also fails to make up for these deficiencies. Gill also fails to disclose or provide a reason for the skilled artisan to arrive at a process "wherein the food is subjected to the treatment pressure for about 5 minutes or less". Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 11-13 and 15-16 for at least this reason.

There is no reason to add a probiotic bacteria of Gill in the process of Kortschack, as suggested by the Examiner, because Kortschack discloses ***deactivating all*** of the bacteria during the high pressure treatment. The methods of Kortschack disclose deactivating the bacteria during the high pressure treatment after the meat product has reached a desired pH. ("The method in accordance with the present invention allows the manufacturer to inhibit the activities of the desirable as well as the undesirable microorganisms at a clearly defined timing by means of the high-pressure treatment." and "In any case the pH will remain stable in the semifinished products subsequent to the high-pressure treatment. There will be no further relevant biochemical processes." Col. 4, ll. 56-60 and 63-65). Thus, the skilled artisan would expect the pressure treatment conditions disclosed in Kortschack to deactivate the probiotic bacteria of Gill. As the skilled artisan would not expect any benefit from using probiotic bacteria in the process of Kortschack they would not make the asserted combination. Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

Further, modifying Kortschack to use a probiotic strain capable of surviving a pressure treatment would modify the principle of operation of Kortschack because, as noted above, Kortschack is explicitly concerned with deactivating all of the bacteria. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Thus, Applicants respectfully request withdrawal of the rejection of Claims 11-13 and 15-16 for at least this reason.

Similarly, with respect to Claim 23, for the reasons discussed above Applicants submit that there is no reason to use the specific probiotic cultures of Gill with the meat processing and pressure treatment methods disclosed in Kortschack. Accordingly, Applicants respectfully request withdrawal of Claim 23 for at least this reason.

**The Examiner's Proposed Combination of Kortschack/Michiels Fails To Make Claims 28-32 Obvious**

Claims 28-32 stand rejected under 35 U.S.C. § 103(a) as obvious over Kortschack in view of GB 2367997 to Michiels et al. (hereinafter "Michiels"). Applicants respectfully traverse the present rejection.

Applicants note that the dependency of Claims 28-32 are corrected to depend from Claim 1. The Examiner found Michiels discloses a pressure treatment with a duration of 1 second to five hours. The Examiner further found that it would have been obvious to treat the food of Kortschack for 5 minutes, 1 minute, or 1 second in order to pasteurize the food product.

Applicants submit that the skilled artisan would have no reasonable expectation of success of using a treatment time of less than 10 minutes in the processes of Kortschack.

Michiels discloses the use of antimicrobial peroxidase for use in conjunction with a pressure treatment step to control microbial growth. Applicants note that Michiels broadly discloses a pressure treatment duration of 1 second to 5 hours. However, the specific examples of Michiels use pressure treatments of 15 minutes.

For example, the pressure treatment in Example 2 of 300 MPa for 15 minutes was insufficient to control bacterial growth. ("[b]ased on the results in this example, use of

superatmospheric pressure in combination with the lactoperoxidase system could be advocated as an effective technique for cold pasteurization, because even using pressures up to 600 MPa, some vegetative bacteria (e.g. *E.coli* MG1655) are insufficiently inactivated.” page 11).

Figure 2 also illustrates that the pressure treatment methods (with a duration of 15 minutes) were unsuccessful to sufficiently reduce the bacteria levels of *E.coli* MG1655.

Thus, Michiels fails to disclose a **successful** pressure treatment with a duration of less than 15 minutes. There is no teaching or suggestion in Michiels or elsewhere that would lead a skilled artisan to believe that a shorter duration treatment would or could be effective in the process of Korschack. Therefore the combination of Michiels and Korschack fails to teach or suggest the combination of features of Claim 1, much less the additional features recited in Claims 28-32. Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

Further, in view of the disclosure in Michiels of the inadequacy of the 15 minute pressure treatment for reducing bacteria, the skilled artisan would have no reasonable expectation of success to reduce the time period of the pressure treatment of Korschack. Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

### **New Claims**

As discussed above, the cited references fail to disclose the features of Claim 1. The cited references also fail to disclose “wherein the selected strain does not cause spoilage of the food” as claimed in Claim 48 and “wherein the selected strain has a viable culture count of at least one hundred thousand colony-forming units per gram after the pressure treatment” as recited in Claim 49.

### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other

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broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: October 15, 2009

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